IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| UNIVERSITY OF MASSACHUSETTS and CARMEL LABORATORIES, LLC<br><br>Plaintiffs,<br><br>v.<br><br>L'ORÉAL USA, INC.<br><br>Defendant. | Civil Action No.17-0868-CFC-SRF |

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**MEMORANDUM OPINION**

April 20, 2021
Wilmington, Delaware

COLM F. CONNOLLY
UNITED STATES DISTRICT JUDGE

Plaintiffs University of Massachusetts and Carmel Laboratories, LLC (collectively, UMass) have sued Defendant L'Oréal USA, Inc. for infringement of U.S. Patent Numbers 6,423,327 (the #327 patent) and 6,645,513 (the #513 patent). Pending before me is L'Oréal's Motion for Summary Judgment of Indefiniteness of the Skin Enhancement Claim Limitation (D.I. 278). L'Oréal argues that claims 1, 3, 5, 6, 7, and 9 of the asserted patents are invalid for indefiniteness. D.I. 278 at 1.

## I. BACKGROUND

The asserted patents teach methods to treat skin using the organic compound adenosine. Each patent has a single independent claim—claim 1 in each patent. For purposes of the pending motion, the patents' independent claims and written descriptions are identical. In each patent, claim 1 recites:

> [a] method for enhancing the condition of unbroken skin of a mammal by reducing one or more of wrinkling, roughness, dryness, or laxity of the skin, without increasing dermal cell proliferation, the method comprising topically applying to the skin a composition comprising a concentration of adenosine in an amount effective to enhance the condition of the skin without increasing dermal cell proliferation, wherein the adenosine concentration applied to the dermal cells is [a recited concentration range].

The two claim 1s differ only with respect to the recited concentration range. In claim 1 of the #327 patent, the recited range of adenosine "applied to the dermal cells" is "$10^{-4}$ M to $10^{-7}$ M." In claim 1 of the #513 patent, the recited range is "$10^{-3}$ M to $10^{-7}$ M."

In their jointly filed claim construction chart, the parties identified the recited concentration range limitation (that is, "wherein the adenosine concentration applied to the dermal cells is [within the recited ranges]") as the only claim term that required construction. D.I. 77 at 2. The parties outlined their respective positions with respect to the recited concentration range limitation in an 82-page joint brief. UMass argued that the limitation should be given its plain and ordinary meaning. L'Oréal argued that the limitation should be construed to mean "wherein the adenosine concentration applied to the skin containing the dermal cells is [within the recited ranges]." D.I. 77 at 2.

The parties' claim construction dispute turned on the meaning of "applied to the dermal cells." L'Oréal argued that those words require the concentration of adenosine to be measured when the adenosine is topically applied to the surface (i.e., epidermal layer) of the skin. UMass argued that the concentration of adenosine is measured at the dermal cells underneath the surface of the skin when the adenosine is absorbed and reaches the dermal cells. I agreed with UMass and concluded that, based on the claim language and intrinsic evidence, the plain and

ordinary meaning of the limitation required the concentration to be measured when the adenosine reached the dermal cells under the surface of the skin.

## II. LEGAL STANDARDS

### A. Indefiniteness

Section 112(b) of the Patent Act requires that the claims of a patent "particularly point[ ] out and distinctly claim[ ] the subject matter which the inventor . . . regards as the invention." 35 U.S.C. § 112(b) (previously § 112 ¶ 2). To satisfy this requirement, a claim must be "sufficiently 'definite.'" *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1348 (Fed. Cir. 2002). "The primary purpose of the definiteness requirement is to ensure that the claims are written in such a way that they give notice to the public of the extent of the legal protection afforded by the patent, so that interested members of the public, *e.g.*, competitors of the patent owner, can determine whether or not they infringe." *Oakley, Inc. v. Sunglass Hut Int'l*, 316 F.3d 1331, 1340 (Fed. Cir. 2003). "[A] patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014). "[A] patent does not satisfy the definiteness requirement of § 112 merely because 'a court can ascribe some meaning to a patent's claims.'" *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed.

Cir. 2014) (quoting *Nautilus*, 572 U.S. at 911). To comply with § 112, a patent "must provide objective boundaries for those of skill in the art." *Id.* Thus, "[t]he scope of claim language cannot depend solely on the unrestrained, subjective opinion of a particular individual." *Datamize, LLC v. Plumtree Software, Inc.*, 417 F.3d 1342, 1350 (Fed. Cir. 2005), *abrogated on other grounds by Nautilus*, 572 U.S. at 901.

"Indefiniteness is a matter of claim construction, and the same principles that generally govern claim construction are applicable to determining whether allegedly indefinite claim language is subject to construction." *Praxair, Inc. v. ATMI, Inc.*, 543 F.3d 1306, 1319 (Fed. Cir. 2008), *abrogated on other grounds by Nautilus*, 572 U.S. at 901. Courts construe claims "as written, not as the patentees wish they had written [them]." *Chef Am. Inc. v. Lamb-Weston, Inc.*, 358 F.3d 1371, 1374 (Fed. Cir. 2004).

**B. Summary Judgment**

A court must grant summary judgment "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). Federal Circuit decisions, however, appear to confirm that I may grant summary judgment based on indefiniteness even when the parties present conflicting expert testimony about whether an artisan of ordinary skill would be able to understand disputed claim terms. *See, e.g.*,

*Halliburton Energy Servs., Inc. v. M-I LLC*, 514 F.3d 1244, 1249–50 (Fed. Cir. 2008) (affirming grant of summary judgment of indefiniteness based on intrinsic evidence and noting in dictum that conflicting expert testimony does not preclude a finding of indefiniteness); *Capital Sec. Sys., Inc. v. NCR Corp.*, 725 F. App'x 952, 958–59 (Fed. Cir. 2018) (affirming district court's decision granting summary judgment of indefiniteness despite expert testimony that an artisan of ordinary skill would understand the disputed claim term with reasonable certainty); *HIP, Inc. v. Hormel Foods Corp.*, 796 F. App'x 748 (Fed. Cir. 2020) (summarily affirming district court's decision granting summary judgment of indefiniteness despite expert testimony that an artisan of ordinary skill would understand the disputed claim term with reasonable certainty).

## III. DISCUSSION

L'Oréal argues that the patents' skin enhancement limitation—that is, the requirement that the composition applied to the skin contain "a concentration of adenosine in an amount effective to enhance the condition of the skin"—is indefinite and renders the patents invalid as a matter of law.

The determination of definiteness begins with "a construction of the claims according to the familiar canons of claim construction." *Oakley*, 316 F.3d at 1340. UMass argues that the skin enhancement limitation should be construed to mean the concentration ranges recited in the "wherein" clause of the asserted claims. *See*

D.I. 315 at 3 (arguing that "'a concentration of adenosine in an amount effective to enhance the condition of skin' does not—as L'Oréal argues—refer to skin that is 'in fact' enhanced, . . . but 'refer[s] back to' the ***concentration***, which is adenosine of 'ten to the negative 4M to ten to the negative 7M' for '327 claim 1" (alterations and emphasis in original) (citation omitted)); D.I. 315 at 4 (arguing that "[t]he concentration's 'effective' amount is plainly '$10^{-4}$ M to $10^{-7}$ M[]' in the [#]327 [patent]"); D.I. 315 at 7 (arguing that "the language 'a concentration of adenosine in an amount effective to enhance the condition of the skin' means . . . a concentration of the recited amount of adenosine"). According to UMass, I "ordered this construction months ago"—i.e., at the claim construction hearing. D.I. 315 at 7.

Truth be told, the parties did not dispute or present for my consideration at the claim construction hearing the skin enhancement limitation and I did not construe the term. UMass now seeks to collapse the skin enhancement limitation into the recited concentration range limitation. But the plain and unambiguous language of the asserted claims makes clear that the skin enhancement limitation is distinct from and independent of the recited concentration range limitation. The skin enhancement limitation requires that the concentration of the adenosine composition that is "*topically appl[ied] to the skin*" be "in an amount effective to enhance the condition of the skin." The recited concentration range limitation

requires that the concentration of the adenosine that reaches and is "*applied to the dermal cells*" be in the recited ranges (i.e., $10^{-4}$ M to $10^{-7}$ M in the case of the #327 patent and $10^{-3}$ M to $10^{-7}$ M in the case of #513 patent).

UMass itself expressly noted the distinction between the two limitations in its claim construction briefing. In UMass's words:

> [T]he claim language twice refers to a "concentration" of adenosine and contrasts the different skin structures the concentration may be "applied" to: a "composition comprising a concentration of adenosine" is "topically applied to the skin," and "the adenosine concentration" is "applied to the dermal cells" in a specific numerical range.
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> "In the patent claim context the term 'comprising' is well understood to mean 'including but not limited to.'" *CIAS, Inc. v. All. Gaming Corp.*, 504 F.3d 1356, 1360 (Fed. Cir. 2007) (discussing cases). Because the "composition" includes, but is not limited to, the recited adenosine concentration, it may also include other ingredients, such as more adenosine that is not ultimately "applied to the dermal cells." *See* Kasting Dec. ¶ 17 (App'x A0251) (opining that only a portion of a topically applied composition "permeates to a particular layer within the skin"). **The claims disclose a numerical range for only the adenosine that is "applied to the dermal cells," and not the amount of adenosine that is in the "composition" itself, except to say that the composition includes, but is not limited to, the amount of adenosine in the concentration that is "applied to the dermal cells."** The claims are directed to what amount of adenosine will be applied to, and thus affect, the dermal cells.
>
> Had the inventors intended the "composition comprising a concentration of adenosine" to include the identical amount of adenosine as what is "applied to the dermal

> cells," they easily could have said so. They did not, instead carefully contrasting "the skin" and "the dermal cells," requiring the recited numerical concentration of adenosine to be "applied to the dermal cells." . . .
>
> According to Defendant, because the claim language provides only one numerical range of adenosine (the "concentration"), but recites that the concentration will be "applied" to "the skin" (as part of the "composition") as well as "the dermal cells" (a layer of the skin), the claims equate the skin and the dermal cells. Defendant's argument defies logic. The claims disclose one numerical concentration of adenosine, which is "applied to the dermal cells." **The composition applied "to the skin" need not be limited to only the recited adenosine concentration.** Indeed, as Defendant recognizes, it often will not contain the same amount because not all adenosine will necessarily penetrate to the dermal layer. *See* Kasting Dec. ¶ 17 (App'x A0251). Instead, the concentration applied "to the skin" includes the amount of adenosine that penetrates to the dermal cells, as well as other ingredients, such as more adenosine, that may not penetrate to the dermal cells. And the claim then specifies the range of the concentration "applied to the dermal cells."

D.I. 97 at 57–59 (bold emphases added).

UMass's claim construction briefing was spot on. The asserted claims do "carefully contrast[] 'the skin' and 'the dermal cells,'" and they do "require[e] the recited numerical concentration of adenosine to be 'applied to the dermal cells,'" not the surface of the skin. UMass was right: The composition that is applied to the skin "need not be limited to only the recited adenosine concentration."

Precisely for that reason, the skin enhancement limitation does not mean "a concentration of the recited amount of adenosine."

How, then, should the skin enhancement limitation be construed? (Although L'Oréal challenges UMass's proposed construction of the skin enhancement limitation, it does not offer an alternative construction.) The limitation requires that the composition applied to the skin have a concentration in an amount that is "*effective* to enhance the condition of the skin." Thus, the adenosine concentration applied to the skin must be in an amount sufficient to achieve the intended result of skin enhancement. *Cf. Abbott Lab'ys v. Baxter Pharm. Prods., Inc.*, 334 F.3d 1274, 1277 (Fed. Cir. 2003) (noting that "effective amount" has a customary usage meaning an "amount sufficient" for the intended result).

The claims do not define what constitutes "enhance[ment] [of] the condition of the skin"; nor do they describe how an artisan of ordinary skill is to ascertain whether a "topical[] appl[ication] to the skin [of] a composition comprising a concentration of adenosine" enhances the condition of the skin. There is a "heavy presumption that a claim term carries its ordinary and customary meaning," *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002), and neither side suggests that an artisan of ordinary skill would have a different understanding of "enhancing the condition of the skin" than a lay person would. When "the ordinary meaning of claim language as understood by a person of skill in the art

may be readily apparent even to lay judges, . . . claim construction . . . involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). The commonly accepted meaning of the phrase "enhancing the condition of the skin"—i.e., improving or making better the quality or desirability of the skin—is clearly indefinite. Indeed, the determination of whether a person's skin is enhanced provides a paradigmatic example of indefiniteness. Beauty, after all, is "in the eyes of the beholder." The assessment of whether a person's skin has been improved is "purely subjective" and "depends on the unpredictable vagaries of any one person's opinion." *Intellectual Ventures*, 902 F.3d at 1381 (internal quotation marks, alterations, and citations omitted).

There is, however, a good argument to be made that the skin enhancement limitation should not be given its plain and ordinary meaning but instead the definition provided in the patents' shared written descriptions. When the written description "reveal[s] a special definition given to a claim term by the patentee that differs from the meaning [the term] would otherwise possess," "the inventor's lexicography governs." *Phillips*, 415 F.3d at 1316. In this case, the patents' written descriptions define "enhancement of skin condition" to mean "a noticeable

decrease in the amount of wrinkling, roughness, dryness, laxity, sallowness, or pigmentary mottling in skin." #327 patent at 2:35–37, *see also id.* at 5:44–48.[1]

The claims do not define or suggest what constitutes a "noticeable decrease" in "one or more of wrinkling, roughness, dryness, or laxity of the skin sallowness, or pigmentary mottling in skin." Nor do they describe how an artisan of ordinary skill would ascertain whether an application of the adenosine resulted in such a noticeable decrease. But here again, the written descriptions are informative. They provide that

> [m]ethods of measuring improvements in skin condition are well known in the art (see, e.g., Olsen et al., J. Amer. Acad. Dermatol. 26:215–24, 1992), and can include subjective evaluations by the patient or a second party, e.g., a treating physician.

#327 patent at 5:48–52. Thus, the written descriptions expressly confirm that the determination of whether the skin enhancement condition is satisfied can be made by purely subjective evaluations of one or more persons.[2] Accordingly, even if I

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[1] Because the written descriptions of the patents are identical in all material respects, I will follow the parties' lead and provide written description citations only for the #327 patent.

[2] I have also considered the patents' prosecution histories and specifically those portions of the histories cited by UMass at pages 5 and 6 of its brief in opposition to L'Oréal's motion. The prosecution histories neither clarify the scope of the skin enhancement limitation nor contradict the written descriptions' express confirmation that determining whether the skin enhancement condition is satisfied can be made by purely subjective evaluations. But even if they had, the written descriptions' express confirmation would nevertheless control. *See Phillips v.*

were to construe the skin enhancement limitation as the term is defined in the written descriptions, the asserted claims would be indefinite.

UMass has effectively conceded that the skin enhancement condition is purely subjective. Its corporate designee, Dr. James Dobson, who is a named inventor of the asserted patents, testified at his deposition that a subjective assessment may be used to determine whether the adenosine has enhanced the condition of the skin within the meaning of the claims:

> **Q.** The fact that you used adenosine on your own skin and observed that there was a decrease in elasticity and a diminution of fine lines and wrinkles, would that have satisfied the patent claims in the [#]327 and [#]513 patent?
> . . .
> **A.** Assuming so, yes.
>
> **Q.** Okay. And the point being is that a subject[ive] assessment of a diminution of fine lines and wrinkles or decrease in elasticity does satisfy or qualify as enhancing the condition of the skin, as you've defined it in the patent; correct? . . .
>
> **A.** Yes.

D.I. 286-1, Ex. 17 at 135:4–18. Perhaps because of this explicit testimony, UMass's expert, Dr. Bozena Michniak-Kohn, did not dispute in her expert reports

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*AWH Corp.*, 415 F.3d 1303, 1317 (Fed. Cir. 2005) (en banc) (noting that "because the prosecution history represents an ongoing negotiation between the [Patent & Trademark Office] and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes").

that a subjective assessment may be used to determine whether the condition of the skin has been enhanced as required by the asserted claims.[3]

In sum, whether I give the skin enhancement limitation its plain and ordinary meaning or the definition set forth in the asserted patents' written descriptions, the term is indefinite. *See Vivid Techs., Inc. v. Am. Science & Eng'g, Inc.*, 200 F.3d 795, 803, (Fed. Cir. 1999) ("[O]nly those terms need be construed that are in controversy, *and only to the extent necessary to resolve the controversy*." (emphasis added)). Artisans of ordinary skill seeking to avoid infringement of the asserted claims would have to guess about the opinions held by doctors, patients, and undefined others with respect to the qualities and desirability of skin conditions. The claims thus lack the requisite objective boundaries required by § 112. *See Datamize*, 417 F.3d 1342, 1352–53 (Fed. Cir. 2005) ("Simply put, the definition of 'aesthetically pleasing' cannot depend on an undefined standard. . . . [Nor can it] depend on the defined views of unnamed persons, even if they are experts, specialists, or academics.").

[3] In its responsive concise statement of facts submitted in support of its opposition to L'Oréal's motion, UMass disputed L'Oréal's statement that Dr. Michniak-Kohn "has not disputed that a subjective assessment may be used to determine whether the condition of the skin has been enhanced." D.I. 319 at 3. UMass cited paragraph of 186 of Dr. Michniak-Kohn's rebuttal report in support of its position. Paragraph 186, however, says nothing about subjective evaluations.

## IV. CONCLUSION

For the reasons discussed above, the skin enhancement limitation, when viewed in light of the specifications and prosecution histories, fails to "inform those skilled in the art about the scope of the invention with reasonable certainty." *Nautilus*, 572 U.S. at 910. The independent claims of the asserted patents are therefore invalid for indefiniteness. As UMass did not argue that the patents' dependent claims provide clarity regarding the scope of the skin enhancement limitation that is lacking in the independent claims, those dependent claims are also invalid for indefiniteness.

The Court will issue an Order consistent with this Memorandum Opinion.